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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
PORTNER, V	
ART UNIT	PAPER NUMBER
1641	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/155,982	Klein et al
Examiner	**Group Art Unit**
Portner	1641

☒ Responsive to communication(s) filed on *Dec 9, 1999* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *17-39* is/are pending in the application.

Of the above, claim(s) *20, 21, 23, 25, 27, 32, and 36* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *17-19, 22, 24, 26, 28-31, 33-35, and 37* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *17-39* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 17-39 are pending. Claims 16-36 have been renumbered under 37 CAR 1.126 to be claims 17-37 respectively and original claims 1-16 have been canceled; claims 17-19, 22,24,26,28-31,33-35,37 are under consideration in so far are the claims recite means and methods of using monoclonal antibodies specific for Taylorella equigenitalis.

Please Note: Newly numbered claim 23 (formerly claim 22) and claim 25 (formerly claim 24) which depend from claim 21(formerly claim 20) which depends from claim 17(formerly claim 16) and claim 27 and 36 will be included in Group III; Claim 23 was included in Group I because it depended from claim 17, but the immunogen or reagent of Claims 23,25, 27 for obtaining the monoclonal antibodies which are capable of interacting with the monoclonal antibodies of Claim 17, is not the same or equivalent immunogen. Therefore claim 23, 25, 27 and 36 are being included in Group III. The phrase "capable of interacting" which is recited in claim 21 was interpreted broadly to mean both antibodies which could be anti-idiotypic antibodies, anti-Fc antibodies as well as antibodies which could interact in a sandwich immunoassay and bind Taylorella epitopes. In light of the confusion due to the broad scope and indefiniteness of the claim in the recitation of the phrase "capable of interacting", the antibodies and the methods of use which depend from claim 21 and claim 17 will be included in Group III, until further clarification is provided, as the specific binding characteristics of the antibodies appear to be

independent and distinct from the those of the antibodies of claim 17 and are not Taylorella epitope specific antibodies.

Election/Restrictions

1. Applicant's election with traverse of Group I, claim(s)17-19, 22, 24, 26,28-29, 30, 31,33-35,37 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that, no arguments were presented. This is not found persuasive because the inventions as claimed are independent and distinct and define patently different inventions. The requirement is still deemed proper and is therefore made FINAL

2. Newly submitted claims 38-39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Group I was elected which was drawn to a monoclonal antibody compositions and a first method of use, wherein the product of claims 38-39 are drawn to a product comprising a protein, produced by a specific process but could be produced by synthetic or recombinant means and a method of using the protein. These inventions are materially independent and distinct from the compositions of Group I which differ by structure, function and effect.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38-39 are included in Group II and stand withdrawn from

consideration as being directed to a non-elected invention. See 37 CAR 1.142(b) and MPEP § 821.03.

3. Claims 20, 27 (in so far as the claim recites the use of an immunogenic protein) and 32, 30,33-34, 38 and 39 (Group II) and claim(s) 21, 23, 25, 27, 36 and 32 (Group III) are withdrawn from further consideration by the examiner, 37 CAR 1.142(b), as being drawn to a non-elected Groups II and III, the requirement having been traversed in Paper No. 6.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/FR97/00649, filed on 4/11/97.

5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

6. If applicant desires priority under 35 U.S.C. 119 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now patent no." should follow the filing date of the parent application. If a parent

application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

7. The first sentence of the specification does not refer to the priority documents upon which Application is based; amendment of the specification to reflect the foreign priority entitled to this Application is requested.

Information Disclosure Statement

8. The information disclosure statement filed have been considered as to the merits prior to first action.

Drawings

9. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

10. This application does not contain an abstract of the disclosure as required by 37 CAR 1.72(b). An abstract on a separate sheet is required.

11. The disclosure is objected to because of the following informalities: a blank line appears at page 24, line 11; the use of abbreviations which have not been defined were found at page 11, line 12 "HAT-DMEM" and page 20, line 29 "ED". Appropriate correction is required.

12. The use of a trademark has been noted in this application at page 24, line 37. It should be capitalized wherever it appears and be accompanied by the generic terminology.

13. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Please Note: Claim dependency should be amended to depend from the appropriate claim as renumbered. Claims dependent from claim 16 should recite --17--;

claims which recite claim 20, should recite --21--;

claims which recite claim 25, should recite --26--;

claims which recite claim 26, should recite --27--;

claims which recite claim 27, should recite --28--;

claims which recite claim 28, should recite --29--;

claims which recite claim 29, should recite --30--. The examiner is reading the claims based upon the corrected dependencies defined above.

Claim Rejections - 35 U.S.C. § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claim 24 is rejected under 35 U.S.C. § 112, first paragraph as failing to provide an enabling disclosure.

As the structural components which define the recited epitopes are not described in the instant specification based upon amino acid structure or conformational components which define the epitopes of the claimed monoclonal antibodies, it is apparent that the claimed hybridoma cell lines are required to practice the claimed invention. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the hybridoma cell lines, see 37 C.F.R. 1.802.

An affidavit or declaration by Applicants, or a statement by an attorney of record stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CAR 1.801-37 CAR 1.809.

17. Claims 17-19, 22, 24, 26-29, 31, 30,33-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected,

to make and/or use the invention commensurate in **scope** with the instantly claimed invention. No specific epitopes or conformational structure(s) which define epitopes have not been described, no written description of specific epitopes of a bacterium whose genus is different from Taylorella or epitopes of Taylorella species which differs from equigenitalis have been described by their amino acid sequence or carbohydrate bonds so as to define the antigenic structures which the claimed monoclonal antibodies specifically bind. Clearly the instant specification teaches and discloses specific monoclonal antibodies which define specific epitopes of Taylorella equigenitalis which was not found in a few other species of bacterium but what specific amino acids or functional groups which define these epitopes (lipopolysaccharide epitopes) are not disclosed. Clearly the epitopes of monoclonal antibodies which are deposited under the terms and conditions of the Budapest Treaty would enable theses epitopes which could be used to define a scope of the claimed invention without undue experimentation through epitope mapping. No other epitopes have been provided original descriptive support and therefore not enabled by the instant specification.

18. Claims 18,19, 22,26-27,30,31, 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a.Claims 17-19 do not recite isolated and purified products and therefore appear to be claiming a product of nature; this rejection could be obviated by amending the claims to recite --Isolated and purified--.

b.Claim 18 recites the phrase "or their fragments"; this does not distinctly claim the invention. Amendment of the claim to recite --Fv, Fab, and F(ab')2 fragments-- could obviate this rejection.

c. Claim 18 recites antibodies which need not specifically bind to the antigens they bind, but need only be capable of binding to the antigen. This does not distinctly claim the invention. Amendment of the claim to recite --specifically-- "binds", could obviate this rejection.

d. Claim 19 recites the phrase " can be obtained from hybrids"; the word "hybrids" should be amended to recite --hybridomas--.

e. Claim 19 recites the phrase "by means of an inactivated strain"; what means this is claiming is not clear. Clarification of this means is requested. Without clarification, the means will be interpreted to be only those specific means disclosed in the instant specification.

f. Claim 19, in paragraph two, the "cloning and selecting according to the capacity of their culture supernatant to recognize an epitope" does not distinctly claim applicant's invention of monoclonal antibodies. The methods step recites that the supernatant recognizes the epitope, the claimed invention relates to monoclonal antibodies which specifically bind to epitopes. The monoclonal antibodies need to be in the supernatant of the culture medium. Amendment of the claim to distinctly claim Applicant's invention could obviate this rejection.

g. Claim 22 recites the phrase "by means of a strain of the species T. equigenitalis or extract(s) from such a strain"; what means this is claiming is not clear, what epitopes these antigen compositions correspond is not distinctly claimed. Clarification of this means is requested. Without clarification, the means will be interpreted to be only those specific means disclosed in the instant specification.

h. Claim 22, in paragraph two, the "screening hybridoma whose culture supernatants exhibit a positive reaction with a bacterium" does not distinctly claim applicant's invention. The methods step recites that the supernatant recognizes the bacterium, but depends from claim 17, which recites that the monoclonal antibody recognizes an epitope. The claimed invention relates to monoclonal antibodies which specifically bind to epitopes not bacterium and fragments thereof. The monoclonal antibodies need to be in the supernatant of the culture medium. The methods steps do not correspond to the preamble of the claim and therefore lack antecedent basis in the preamble and claim 17 from which it depends. The reactivity is not distinctly claimed as claim 17 recites the need to react with non-cross reactive epitopes but claim 22 recite any type of reactivity for T. equigenitalis. The claim does not distinctly claim Applicant's invention.

i. Claim 26 and 31 recite the phrase "at least one monoclonal"; it is not clear how many monoclonal antibodies are being added as no upper limit is being recited. Clarification is requested.

j. Claim 28 recites the phrase "one or more monoclonal antibodies"; it is not clear how many monoclonal antibodies are being added as no upper limit is being recited. Clarification is requested.

k. Claim 26 detects "any product formed"; the product formed could be a non-specific product which is not indicative of bacterial infection due to T. equigenitalis, the product could be formed due to agglutination and precipitation of the antibodies added to the sample and would not result in the identification of T. equigenitalis in the specimen or culture. Therefore, detecting **any product** does not distinctly claim the invention. The antigen is not clearly defined and depends from claim 17 which recites an epitope/antibody interaction. Clarification of the antigen and the epitopes participating in the reaction is requested.

l. Claim 30 recites non-elected subject matter and therefore does not distinctly claim applicant's invention. Amendment of the claims to recite the elected subject matter could obviate this rejection.

m. Claim 35 recites the phrase "blocked by saturation of the specimen obtained by means of a serum from which anti-T. equigenitalis antibodies have been removed"; the meaning of these claim limitations are not clear. Monoclonal antibodies are not serum antibodies but may be obtained from culture supernatants or from ascites fluid which may contain serum. What is being used to saturate the sample is not distinctly claimed.

Claim Rejections - 35 U.S.C. § 102

n. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

o. Claims 17,19, 22, 24, 26, 28, rejected under 35 U.S.C. 102(b) as being anticipated by Friedrich (1995).

Friedrich disclose monoclonal antibodies which specifically bind to Taylorella equigenitalis, wherein the monoclonal antibodies were used in diagnostic methods for the identification of contagious equine metritis (CEM) and states "[M]onoclonal antibodies not only allow a prompt diagnostic of CEM but also give a better proof." The specimens analyzed were taken from the urogenital-tract and the accessory lymph nodes from Shetland pony-stallions and Taylorella equigenitalis was found in the vesicula seminalis and the testicles. Inherently the reference discloses diagnostic monoclonal antibodies produced by hybridomas, wherein the monoclonal antibodies specifically bind to Taylorella equigenitalis expressed surface antigens, and provided means for diagnosis of infection in specific biological specimens. Interaction between the monoclonal and the bacterial antigens provided for better diagnostic proof of infection. Therefore the reference anticipates the now claimed invention.

19. Claims 17, 18, 19, 22, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Akuzawa et al (1996).

Akuzawa et al disclose two monoclonal antibodies which specifically bind to Taylorella equigenitalis, wherein the monoclonal antibodies were designated Mab NA-1 and NA-2. Monoclonal antibody Mab Na-1 recognized an antigen of about 28-44 kDa. The relative molecular weight of the antigens of Akuzawa et al is within the acceptable range of variance for antigens and therefore reads on the now claimed approximate 52.7 kDa antigen (claim 18). Inherently the reference discloses monoclonal antibodies produced by hybridomas, wherein the monoclonal antibodies specifically bind to Taylorella equigenitalis expressed surface antigens and anticipates the now claimed invention.

Claim Rejections - 35 U.S.C. § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Friedrich (1995). as applied to claim 17,19, 22, 24, 26, 28 above, and further in view of Sugimoto et al (1988)

See Friedrich et al above. Friedrich show monoclonal antibodies to Taylorella equigenitalis and teach the use of the monoclonal antibodies in diagnostic methods for determining the presence of the bacterium and infection but differs from the instantly claimed invention by failing to show monoclonal antibodies to antigen of about 52.7 kDa.

Sugimoto et al show Taylorella equigenitalis outer membrane antigens, both protein and lipopolysaccharide antigens, to include antigens from about 29 kDa to greater than 200 kDa (see Figure 3, page 166, column 1) in an analogous art for the purpose of purifying the outer membrane, analyzing it biochemically (page 164, introduction section, column 1) and immunologically to lay the ground work for more specific serological tests for contagious equine metritis (page 167, last paragraph).

Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to obtain monoclonal antibodies for Taylorella equigenitalis antigens, as taught by Friedrich in view of the teachings of Sugimoto to include monoclonal antibodies to antigens of about 52.7, 120 and 150 kDa because Sugimoto teach antigens of the outer membrane of Taylorella equigenitalis which were immunogenic and reactive with antibodies in biological samples post infection, and the immunoblot shown in Figure 3, clearly show antibodies reactive Taylorella antigens of about 52.7 kDa, 120 kDa and 150 kDa. The person of ordinary skill in the art would have been motivated to obtain immunologically specific diagnostic tools because Friedrich teaches that monoclonal antibodies provide better proof of infection and Sugimoto shows diagnostic antigens which are immunoreactive with antibodies present in a biological sample.(In decision Ex parte Erlich 3 USPQ2d 1011, case law was established for obviousness; specifically, it is obvious to make a monoclonal antibody to a known antigen for the purpose of attaining improved specificity of antibody binding.)

22. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Friedrich (1995). as applied to claim 17,19, 22, 24, 26, 28 above, and further in view of Corbel et al (1982)

See Friedrich et al above. Friedrich show monoclonal antibodies to Taylorella equigenitalis and teach the use of the monoclonal antibodies in diagnostic methods for determining the presence of the bacterium and infection but differs from the instantly claimed invention by failing to show monoclonal antibodies to antigen of about 52.7 kDa.

Corbel et al show Haemophilus (Taylorella) equigenitalis major antigens, both protein and polysaccharide antigens, two polysaccharide antigens were identified, one of which was about 18 kDa (page 535, paragraph 5) in an analogous art for the purpose of purifying antigen components from this organism and analyzing it biochemically and immunologically for contagious equine metritis diagnosis.

Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to obtain monoclonal antibodies for Taylorella equigenitalis antigens, as taught by Friedrich in view of the teachings of Corbel to include monoclonal antibodies to antigens of about 22 (LPS) kDa because Corbel teach antigens of the outer membrane of Taylorella equigenitalis which were immunogenic reactive with antibodies, wherein one of the antigens of Corbel was characterized as a subunit or precursor of the lipopolysaccharide-protein complex (page 536, paragraph 3, last two lines) clearly teaches antibodies reactive Taylorella antigens. The person of ordinary skill in the art would have been motivated to obtain immunologically specific diagnostic tools because Friedrich teaches that monoclonal antibodies

provide better proof of infection and Corbel teaches a polysaccharide antigen which is on the outer surface of the bacterium which could be used as a diagnostic antigen which would be immunoreactive with monoclonal antibodies raised thereto as suggested by Friedrich. (In decision Ex parte Erlich 3 USPQ2d 1011, case law was established for obviousness; specifically, it is obvious to make a monoclonal antibody to a known antigen for the purpose of attaining improved specificity of antibody binding.)

23. Claims 17, 19, 22, 24, 26, 28-29, 31, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tainturier et al (1981) in view of Friedrich (1995) and Harlow:Antibodies, A Laboratory Manual (1988,chapters 4,6,9, 14-15).

Tainturier et al teach antibodies and methods of specifically detecting Haemophilus (also know as Taylorella) equigenitalis in a biological sample and shows antibodies which only reacted with Haemophilus (also know as Taylorella) equigenitalis (Table 3, page 359). Tainturier et al differs from the instantly claimed invention by failing to show the use of monoclonal antibodies specific for Haemophilus (also know as Taylorella) equigenitalis antigen.

See discussion of Friedrich above. The reference teaches the production of monoclonal antibodies for Haemophilus (also know as Taylorella) equigenitalis and their use in an analogous art for the purpose of obtaining specific diagnostics which provide for better proof of infection.

Harlow et al teach specific means, methods and reagents for the production of monoclonal antibodies and methods of using said monoclonal antibodies in an analogous art for the purpose of

obtaining a ready source of antibodies which evidence increased antigen specificity, as well as immunoassay methods which utilize at least one monoclonal antibody and one or more antibodies, wherein the immunoassay methods comprise a washing step to remove any unbound antibodies and the use of a blocking solution to prevent non-specific binding of antibodies to container surfaces. Harlow teaches monoclonal antibody compositions in phosphate buffered saline are useful in immunoassay methods (see page 580) and therefore teaches compositions of at least one monoclonal and a pharmaceutically inert vehicle (see chapter 14, page 580, section 3).

Therefore, it would have been prima facie obvious to the person of ordinary skill in the art at the time the invention was made to modify the method of Tainturier et al in view of the teaching of Friedrich and Harlow because Friedrich teaches H. equigenitalis monoclonal antibodies provide for better proof of diagnosis of infection when analyzing biological samples and Harlow teaches specific methods steps of injection of a host with antigen, fusion of spleen cells to obtain hybridoma, screening of hybridoma-antibody producing cell lines, up scaling for the attainment of larger quantities of antibody, methods of purifying monoclonal antibodies and the application of monoclonal antibodies to immunoassay methods for the attainment of accurate test results. In the absence of a showing of unexpected results, the person of ordinary skill in the art at the time the invention was made would have been motivated by the reasonable expectation of success of obtaining monoclonal antibodies which are specific for the diagnosis of contagious equine metritis because Tainturier et al and Friedrich both are directed to the accurate diagnosis of this disease and Friedrich teach that monoclonal antibodies directed against the pathogen

which caused CEM results in a better proof of infection and Harlow teach that monoclonal antibodies provide for increased assay sensitivity and a ready source of antibody, as well as teach the importance of blocking non-specific binding using serum, or other known blocking solution (see page 496 and page 581, Notes section) to obtain the most accurate immunoassay results possible.

24. Claims 30,33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tainturier in view of Friedrich and Harlow as applied to claims 17, 19, 22, 24, 26, 28-29,35 and 37 above, and further in view of Foster (US Pat. 4,444,879).

See discussion of the cited references above. Tainturier in view of Friedrich and Harlow teach the production of immunoassay that are specific for diagnostic purposes, to include the production of T. equigenitalis specific antibody compositions, to include monoclonal antibodies directed against T. equigenitalis antigen but differs from the instantly claimed invention by failing to show the immunoassay components into kit form.

Foster et al teach the formulation of immunoassay reagents into kit form to include instructions to carry out the intended use of the kit (see Figure 6).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to compile the monoclonal antibodies of Friedrich et al into kit form and comprising all the necessary immunological reagents and blocking reagents as taught by Harlow because Foster shows kits are art

recognized as a convenient way to compile the necessary components for an immunological method and container housings are necessary components of a kit to hold essential method reagents and including the instructions for carrying out the preferred method. Kits are also art recognized for providing a convenient way to provide assay reagents and components for commercial distribution to research and medical concerns interested in the immunological assay and would comprise the monoclonal antibodies of Friedreich in light of the increased sensitivity and specificity possible from monoclonal antibodies. Ex parte Erlich, 3USPQ2d 1011, 1015 (CAFC 1987).

Conclusion

25. This is a non-final rejection.

26. No arguments are of record with respect to the genetic and structural uniqueness of the monoclonal antibodies of the instant invention; no specific monoclonal antibodies produced by genetically unique hybridomas which have been deposited are now claimed.

27. No claims are allowed.

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

29. Mazurova (1985) is cited to show serological diagnostic methods for Taylorella equigenitalis.

30. Sahu et al (1983) is cited to show various serotests for Taylorella equigenitalis.

31. McBeath et al (1983) is cited to show equine immunology and the development of vaccines.

32.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be changing February 7, 1998. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

James C. Housel

JAMES C. HOUSEL 12/31/99

SUPERVISORY PATENT EXAMINER